DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Institute of Dental and Craniofacial Research

National Advisory Dental and Craniofacial Research Council

Summary Minutes

Date: January 28, 2002
Place: Building 45, Conference Room E-1 & 2
National Institutes of Health
Bethesda, Maryland 20892

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

MINUTES OF THE
NATIONAL ADVISORY DENTAL AND CRANIOFACIAL RESEARCH COUNCIL

January 28, 2002

The 167th meeting of the National Advisory Dental and Craniofacial Research Council (NADCRC) was convened on January 28, 2002, at 8:30 a.m., in Building 45, Conference Room E 1 & 2, National Institutes of Health (NIH), Bethesda, Maryland. The meeting was open to the public from 8:30 a.m. to 11:30 a.m., followed by the closed session for Council business and consideration of grant applications from 11:30 a.m. until adjournment at 4:30 p.m. Dr. Lawrence A. Tabak presided as Chair.

Members Present:

Dr. John Alderete
Dr. Samuel F. Dworkin
Dr. Raymond Fonseca
Dr. Jay Alan Gershen
Dr. Harold Morris
Dr. Linda C. Niessen
Dr. Joan Reede
Dr. Dianne E. Rekow
Dr. Martha J. Somerman
Ms. Kim S. Uhrich

Members of the Public Present:

Mr. Jack Bresch, Associate Executive Director, American Dental Education Association (ADEA), Washington, DC
Dr. Aida Chohayeb, Professor, Howard University, Washington, DC
Dr. Robert J. Collins, Deputy Executive Director, American Association for Dental Research (AADR), Alexandria, VA
Dr. Karl Haden, Associate Executive Director for Educational Policy and Research, ADEA, Washington, DC
Ms. Gina Luke, Director, State Government Relations and Advocacy Outreach, ADEA, Washington, DC
Dr. William Maas, Director, Division of Oral Health, Centers for Disease Control and Prevention, Chamblee, GA
Ms. Myla Moss, Director, Congressional Relations, ADEA, Washington, DC

Mr. Jonathan Schuermann, Ph.D. Candidate, University of Missouri, Columbia, MO
Dr. Eli Schwarz, Executive Director, AADR and International Association for Dental Research Alexandria, VA
Ms. Julie Scott, Manager, Legislative and Regulatory Policy, American Dental Association, Washington, DC

Federal Employees Present:

National Institute of Dental and Craniofacial Research:

Dr. Lawrence Tabak, Director, NIDCR
Dr. Dushanka V. Kleinman, Deputy Director, NIDCR, and Director, Division of Population and Health Promotion Sciences (DPHPS)
Dr. Margo Adesanya, Senior Scientist and Program Director, Patient-Oriented Research Program, DPHPS
Ms. Carolyn Baum, Committee Management Specialist and Council Secretary, Office of the Director (OD)
Dr. Henning Birkedal-Hansen, Scientific Director, NIDCR, and Director, Division of Intramural Research (DIR)
Dr. Norman S. Braveman, Assistant to the Director, OD
Dr. Patricia S. Bryant, Health Scientist Administrator and Program Director, Behavioral and Social Science Research Program, DPHPS
Dr. Maria Teresa Canto, Health Scientist Administrator and Program Director, Population Studies Program, DPHPS
Dr. Lois K. Cohen, Associate Director of International Health, NIDCR, and Director, Office of International Health (OIH)
Mr. George J. Coy, Chief, Office of Administrative Management (OAM)
Dr. Wayne Deutsch, Dental Public Health Resident, DPHPS
Ms. Yvonne du Buy, Associate Director for Management, Executive Officer, OAM
Dr. Caswell Evans, Director, National Oral Health Initiative, OD
Mr. William Foley, Grants Management Specialist, Division of Extramural Activities (DEA)
Dr. Philip Fox, Consultant, DPHPS
Dr. Isabel Garcia, Special Assistant for Science Transfer, Office of Communications and Health Education (OCHE), and Co-Director, NIDCR Dental Public Health Residency Program
Ms. Christen Gibbons, Computer Specialist, Office of Information Technology (OIT)
Dr. Kevin Hardwick, International Health Officer, OIH
Dr. George Hausch, Acting Director, DEA
Ms. Deane Hill, Contractor, Office of Science Policy and Analysis (OSPA)
Dr. Alice Horowitz, Senior Scientist, DPHPS
Ms. Lorrayne Jackson, Extramural Research Coordinator and Outreach Specialist, DPHPS
Mr. William M. Johnston, Consultant, Division of Basic and Translational Sciences (DBTS)
Dr. Albert Kingman, Chief, Biostatistics Core, DPHPS
Dr. Eleni Kousvelari, Chief, Cellular and Molecular Biology, Physiology, and Biotechnology Branch, DBTS
Ms. Wendy A. Liffers, Director, OSPA

Dr. James A. Lipton, Acting Deputy Director, DPHPS, and Director, Research Training and Career Development Program, DPHPS
Dr. Jack London, Deputy Scientific Director, DIR
Dr. Yujing Liu, Scientific Review Administrator, DEA
Ms. Carol Loose, Budget Analyst, OAM
Dr. Dennis F. Mangan, Chief, Cellular and Molecular Biology Branch, DBTS
Dr. J. Ricardo Martinez, Executive Secretary, NADCRC, and Associate Director for Program Development, OD
Mr. Thomas Murphy, Acting Chief, OIT
Dr. Ruth Nowjack-Raymer, Health Scientist Administrator and Program Director, Health Disparities Research Program, DPHPS
Dr. Robert Selwitz, Senior Epidemiologist and Co-Director, NIDCR Dental Public Health Residency Program, DPHPS
Dr. Ann L. Sandberg, Acting Director, DBTS
Dr. Anna Sandberg, Scientific Review Administrator, Division of Research Activities (DRA)
Dr. Yasaman Shirazi, Health Scientist Administrator, DBTS
Dr. Rochelle Small, Health Scientist Administrator, DBTS
Ms. Cheryl Stevens, Special Assistant for Operations, OD
Mr. Robert Tarwater, Grants Management Specialist, DRA
Ms. Tracy Walker, Secretary, OSPA
Dr. Philip Washko, Scientific Review Administrator, DRA
Ms. Mary Ann Williamson, Computer Specialist, OIT
Dr. Guo H. Zhang, Health Scientist Administrator, DBTS
Ms. Amy Zukowski, Budget Analyst, OAM

Other Federal Employees:

Dr. C. R. Buchanan, Acting Assistant Medical Director for Dentistry, Department of Veterans Affairs, Washington, DC
Dr. Robert Mecklenburg, Consultant, National Cancer Institute, NIH

OPEN PORTION OF THE MEETING

I. CALL TO ORDER

Dr. Lawrence A. Tabak, Director, NIDCR, called the meeting to order. He welcomed all attendees and asked them to introduce themselves. Dr. J. Ricardo Martinez, Executive Secretary, announced two recent changes by Council members. Dr. Jay Gershen has returned to his former position as Executive Vice Chancellor, University of Colorado, Denver. Dr. Joan Reede has been appointed Dean for Diversity and Community Partnerships, Harvard Medical School, Boston, Massachusetts, and is a member of the Board of Regents for the NIH Clinical Center. The Council confirmed approval of the committees' operating procedures.

II. APPROVAL OF MINUTES

The minutes of the Council's meeting on September 24, 2001, were considered and unanimously approved.

III. FUTURE COUNCIL MEETING DATES

The following dates for future Council meetings were confirmed:

June 10-11, 2002
September 26-27, 2002

February 3-4, 2003
June 16-17, 2003
September 18-19, 2003

IV. REPORT OF THE DIRECTOR

Dr. Tabak highlighted several items from the written Director's Report (see Attachment III). He reported that he continues to meet with students and junior faculty and to give presentations on oral health research at U.S. dental schools.

DHHS/NIH/NIDCR Activities. Dr. Tabak said that, during the recent bioterrorism events, the NIDCR served as the location of the Chief Dental Officer, Dr. Dushanka V. Kleinman, for U.S. Public Health Service activities. Dentists in the Commissioned Corps were involved in identifying victims and conducting epidemiological investigations and triage diagnostics.

In early November, the NIH launched its Stem Cell Registry and plans to make the first awards for embryonic stem cell research during fiscal year (FY) 2002. The registry may be viewed at http://escr.nih.gov, and questions may be addressed to stemcellregistry@od.nih.gov.

On December 7, Dr. Andrew von Eschenbach was appointed Director of the National Cancer Institute, NIH.

Scientific Advances. Dr. Tabak noted two of the many scientific advances made by NIDCR scientists in recent months. Investigators in the Division of Intramural Research (DIR) have created a mouse model for amelogenesis imperfecta, a dental defect that occurs in approximately 1 in 14,000 individuals and results in abnormally formed tooth enamel. This achievement was reported recently in the *Journal of Biological Chemistry* (June 13, 2001). With the animal model, scientists will be able to study the development of the disorder and the formation of enamel. Dr. Ashok Kulkarni and colleagues in the Functional Genomics Unit genetically engineered mice by deleting the gene responsible for producing amelogenin, the most abundant protein in enamel. This animal model is the first one in which scientists have knocked out a tooth-specific gene.

NIDCR-supported scientists also have discovered a key signaling protein, a so-called adaptor protein that acts as a platform for other proteins which anchor and form complexes that influence the transmission of signals through cells. Dr. Jonathan Zonana, an NIDCR-supported researcher at Oregon Health and Science University, Portland, and his international colleagues determined that the adaptor protein inserts itself early into the signaling process and "acts as a critical bridge" between upstream receptors and downstream proteins. This discovery, which was reported in *Nature* (December 20, 2001), provides important insights on protein interactions and may help to explain the variability of hypohidrotic ectodermal dysplasia (HED) in individuals and to improve understanding of the normal development of teeth and other ectodermal tissues.

Meetings and Workshops. Dr. Tabak highlighted three recent meetings. On October 30-31, 2001, the NIDCR hosted the Dental Deans Meeting in Bethesda, MD, in coordination with the major American dental professional associations. The meeting, entitled "Conducting and Putting Science Into Practice: The Critical Role of Dental Schools," was attended by deans and associate deans for research from 44 U.S. dental schools and 6 Canadian dental schools and by 18 senior officials from parent universities or academic health centers.

The NIDCR also had key roles in planning two national initiative meetings related to the objectives for oral health promotion and disease prevention outlined in Healthy People 2010 and the Surgeon General's report on oral health. The purpose of one meeting was to provide approaches and models for achieving progress toward the objectives, to state, local, and national leaders, and to address research opportunities and mechanisms. The purpose of the other meeting was to convene the representatives of more than 90 professional, voluntary, and private organizations who have been charged by the Surgeon General to develop a National Oral Health Plan by the summer of 2002.

On December 11-13, 2002, the NIDCR and the Food and Drug Administration hosted the second Dental, Oral, and Craniofacial Technology Forum at the NIH. More than 60 representatives of Federal agencies, industry, professional and scientific societies, advocacy groups, and educational associations attended the forum. The aims of the fora are to improve the translation of research results into new dental products, to foster effective interactions among the groups, and to promote successful clinical trials.

Extramural Update. Dr. Tabak reported that Dr. John A. Klingensmith, an NIDCR grantee at Duke University Medical Center, Chapel Hill, North Carolina, recently was selected to receive a Presidential Early Career Award for Scientists and Engineers (PECASE). Dr. Klingensmith is being recognized for his accomplishments in developmental biology. In mouse models, he has shown that certain features of development may be implicated in craniofacial and neural tube malformations. As reported in *Nature* (February 10, 2000), he and his colleagues showed that the combined absence of two genes (*chordin* and *noggin*) leads to severe defects in head formation that closely resemble various human birth defects (e.g., spina bifida). In collaboration with clinical geneticists, the researchers are assessing the state of these genes in patients who have birth defects that correspond to those observed in the mouse.

International Activities. On October 22, 2001, the NIDCR and the Fogarty International Center, NIH, cosponsored the first David E. Barmes Global Health Lecture. The honorary lecturer was Dr. Arthur Caplan, Director, Center for Bioethics, University of Pennsylvania, Philadelphia, who spoke on "Ethical Issues on the Biomedical Frontier." The lecture was webcast and videotaped and can be viewed at http://videocast.nih.gov/PastEvents.asp?c=4.

The NIDCR produced a new videotape, "Science Knows No Country: NIDCR's Global Mission." The videotape was shown during the David E. Barmes Global Health Lecture and was viewed by the Council members during the meeting (see section VIII below). Dr. Tabak commented that the video is first-rate and received the coveted "Freddie," or first prize, in the category of Dentistry, from Time Inc. Health as one of its 2001 International Health & Medical Media Awards.

Personnel Changes. Dr. Raymond Dionne, Senior Investigator, recently was named Chief, Pain and Neurosensory Mechanisms Branch, DIR. Dr. Tabak noted that this appointment reflects his and the Scientific Director's commitment to strengthen pain research at the NIDCR and to move quickly toward building a translational pain research program at the NIH. Translational pain research is an important part of the intramural portfolio, and Dr. Dionne, who started this initiative, now has the opportunity to expand the program.

Additional information on these and other NIDCR activities is provided in the written Director's Report (Attachment III).

V. OVERVIEW OF THE FY 2001 BUDGET

Dr. Tabak presented his first annual update of "the year that was." He reviewed NIDCR's budget, commitments, and initiatives in FY 2001 and plans for the future. The aim is to help the Council better understand NIDCR's programs, activities, and operations.

In FY 2001, the NIDCR's budget totaled approximately $306.2 million. The overwhelming majority of these monies (approximately $233.2 million) supported extramural research, whereas smaller amounts supported intramural activities (approximately $55.7 million) and research management and support (approximately $17.3 million).

Most of the funds allocated to extramural research supported research grants (approximately $209.7 million, 772 grants), and most of these were noncompeting research projects (approximately $117.7 million, 435 projects). Other mechanisms of extramural support included competing and supplemental research projects, small business research awards, research centers, research and development contracts, research training (i.e., National Research Service Awards), and other research support (i.e., for career development, minority research training, and related research). The percentage distribution of extramural funds in FY 2001 was as follows: 77 percent to research project grants (RPGs), 8 percent to research centers, 6 percent to contracts, 5 percent to other research support, and 4 percent to research training. Most of the funds (83 percent) were already committed to ongoing projects, and only 17 percent was discretionary (i.e., available for meeting emerging

opportunities and needs). Of the funds for RPGs only, 69 percent was already committed and 31 percent was discretionary.

In addition, the NIDCR contributes a portion of its extramural funds each year for various taps and assessments by the NIH, which are made in proportion to an institute or center's (IC's) funding. In FY 2001, the NIDCR contributed approximately $24.6 million in support of NIH's central resources (the management fund and rent), the NIH information technology (IT) enterprise and central IT taps, NIH-wide program evaluation, NIH administration of NRSA training programs, NIH study sections, and other miscellaneous taps.

Of the total funding for intramural activities in FY 2001, approximately $38.7 million supported research conducted in DIR. The remaining funds were allocated for central NIH assessments, assessments for NIH facilities, IT development, and renovation of DIR laboratories in building 30.

Dr. Tabak noted that the NIDCR was able to utilize its funding to support several exciting initiatives in FY 2001. For example, in collaboration with other ICs, the NIDCR funded five centers to reduce oral health disparities. The Institute also funded five awards to develop state models for oral cancer prevention and early detection, nine awards for research on HIV/AIDS-associated oral viral infections, three supplemental awards to support *Candida* DNA microarray facilities, six awards for research on oral microbiology and immunology of type I diabetes, and nine recompeted NRSA institutional awards. However, because of limited funds, the NIDCR was not able to issue a proposed Request for Applications (RFA) on salivary diagnostics and had to place a moratorium on new program project grants (P01s) and reduce the amount of recompeted grant awards by 5 to 15 percent.

For FY 2002, the NIDCR has set a series of goals—to increase clinical research, capitalize on extramural advances in bioengineering, and promote research on HIV/AIDS. The NIDCR is supporting the development of clinical trials; Specialized Programs of Research Excellence (SPORE), in collaboration with the National Cancer Institute; a temporomandibular (TMD) registry of patients with TMD devices; research on health disparities; and enhancement of the infrastructure of minority dental schools. The NIDCR also is supporting research on stem cell biology and, on January 2, released the RFA for "Development of Technologies for Saliva/Oral Fluid-based Diagnostics." In addition, the NIDCR has issued an RFA for research on the oral transmission of HIV/AIDS.

In closing, Dr. Tabak highlighted some broad, general directions for NIDCR research in the future. The areas of interest include application of biomimetics and stem cell biology to restoration of oral tissues, modeling of complex diseases, research on biofilms, identification of novel genes involved in craniofacial disorders, studies of molecular anatomy and proteomics, strengthening of the interface between molecular epidemiology and clinical genetics, establishment of a registry of patients with Sjögren's syndrome, and development of an oral mucosal vaccine against HIV infection.

VI. UPDATES

Dr. Martinez, as Associate Director for Program Development, Office of the Director (OD), NIDCR, presented three items: suggested topics for upcoming NADCRC meetings, activities of NIDCR's Scientific Opportunities Work Group, and initiatives to enhance dental schools' participation in

research. Dr. Martinez provided the Council with a list of suggested topics for its June 2002 - June 2003 meetings, and he asked the Council to establish a subcommittee to help develop agendas for future meetings.

NIDCR Scientific Opportunities Work Group. Dr. Martinez noted that the Scientific Opportunities Work Group was established and charged by Dr. Tabak to identify and catalog key scientific opportunities for 2004-09 to provide the scientific framework for NIDCR's development of year-to-year initiatives during the budget-justification process and for NIDCR's long-range planning. The Work Group, which consists of staff members from each NIDCR division, has identified three major topics of opportunity: (a) genomics and proteomics of oral, dental, and craniofacial diseases; (b) bioengineering of oral, dental, and craniofacial tissues; and (c) clinical and community-based approaches to diagnosis, prevention, and treatment of disease. Five specific challenges highlighted by the Work Group are to understand the molecular, genetic, and behavioral mechanisms of oral, dental, and craniofacial diseases; characterize genetic polymorphisms and delineate the interaction between genetic and environmental factors in disease; develop new and effective therapeutic approaches; improve diagnostic technologies to monitor the progression of disease and the efficacy of intervention trials; and develop and test new and effective measures of health promotion and disease prevention for communities and individuals.

Dr. Martinez noted that the Work Group plans to prepare a summary of its findings by late spring 2002 and to have a revised plan for presentation to the Council at its June meeting. Between February and April 2002, staff will convene several small colloquia of experts from the NIH and extramural community in specific areas.

In discussion, Dr. Tabak clarified that initiatives related to bioterrorism are embedded in NIDCR's activities in the short term and will be included in the challenges identified for the long term. Responding to a request that the extramural community be involved earlier in NIDCR's program planning, Dr. Tabak stated that an NIDCR goal is to make its long-range planning more transparent, inclusive, and involving of the extramural community at earlier stages, before proceeding to develop its initiatives.

Dental Schools' Participation in Research. Dr. Martinez emphasized the importance of enhancing and maintaining the capability of dental schools to participate fully in the modern research enterprise. As previously noted by Dr. Tabak (see section IV), the NIDCR collaborated with several professional and education organizations to sponsor a meeting of dental school deans, associate deans for research, and senior university officials on October 30-31, 2001. At this meeting on "Conducting and Putting Science Into Practice: The Critical Role of Dental Schools," the participants convened into 13 breakout groups to address four major topics: role and importance of research and scholarship in dental education and practice; cost, workforce needs, and infrastructure requirements for basic and clinical research; recruitment and retention of students and faculty into research careers; and partnerships that can be established to enhance research in dental schools. The groups generated a set of general proposals directed to dental schools, the NIDCR and NIH, and professional organizations [the American Dental Education Association (ADEA), American Dental Association (ADA), and American Association for Dental Research (AADR)]. Dr. Martinez summarized the proposals, which were presented previously at the ADEA-sponsored dean's conference in Scottsdale, Arizona, and will

be considered again at the March 2002 meetings of the AADR, ADA, and ADEA in San Diego, California.

Important "next steps" to be taken include (a) NIDCR coordination of regional workshops to inform dental school faculty and students about research and training opportunities; (b) promotion of self-study needs assessments by interested schools, which could include site visits and technical assistance; (c) documentation of "best-practice" models; and (d) development of a joint plan of action for NIDCR, ADEA, ADA, and AADR to develop and implement initiatives (e.g., an RFA) that would enhance research in dental schools. As part of this follow-up, a concept clearance for awards to enhance the research capacity of dental schools was presented to Council (see section VII below). Dr. Martinez noted that staff from the National Center for Research Resources (NCRR), NIH, participated in the October 2001 meeting and, at NIDCR's encouragement, included dental schools in its reissued RFA for Centers of Biomedical Research Excellence (COBRE). Eleven U.S. dental schools in 9 of the 23 states receiving Institutional Development Awards (IdeAs) from the NIH would be eligible to respond to this RFA. Dental and veterinary schools will not be subject to NCRR's restrictions limiting states to only two applications. The NIDCR has contacted the 11schools to encourage them to respond to this significant opportunity and to submit applications.

Discussion

The Council commended the NIDCR for its outstanding initiatives to enhance research at dental schools and noted the importance of also fostering interactions between dental schools and their parent universities or academic health centers. Dr. Tabak agreed that all partners need to be "thoroughly engaged," and he noted that the possibility of universities providing matching funds for NIDCR awards was discussed at the October 2001 meeting. He said that the NIDCR is cognizant of the need to both offer opportunities *and* specify requirements for linkages with other components of academia. Dr. Martinez and Dr. Raymond J. Fonseca, who represented the Council at the meeting, noted that the participants at the meeting emphasized the need for partnerships at local, regional, and global levels. The Council commented that partners, which could include small, local companies, would want to be assured that they receive credit for their participation.

Referring to the research challenges identified by the NIDCR Scientific Opportunities Work Group, the Council suggested that the "research enterprise is way ahead of the troops" and that partnerships with dental professional associations and organizations are imperative for developing and reforming the curricula offered in dental schools. It was noted that the ADEA and AADR are addressing curriculum reform and that the ADEA is supporting development of model curricula for dental schools. Dr. Tabak agreed that the overall challenge is to "infuse more science into the practice of dentistry." Possible strategies raised by the Council include use of NIH's R25 mechanism for the redesign of curricula, NIDCR collaboration with other ICs to leverage its resources to increase overall support for dental schools, linkage of NIDCR's research training opportunities with those of other ICs and organizations to assure support for training at all career stages, provision of leadership training and mentorship for research administrators, and facilitation of discussions of this topic among the dental professional organizations and with the NIDCR.

Dr. Tabak suggested that the Council could provide specific input, at its June 2002 meeting, on the interests of dental schools and students, dental schools' priority needs, and strategies for engaging

students in science. The Council noted that medical and dental students have different "mindsets," for the vast majority of first-semester dental students are focused on becoming "hands-on" dental practitioners, rather than developing expertise in a particular discipline or field. New strategies are needed to identify and recruit students who are interested in research. Efforts are also needed to increase the awareness of the public and of allied health professionals that dental care is a medical need.

The Council suggested that two different approaches may be needed to enhance research at dental schools: (a) creation of a "research ethos" among dental schools that have a vigorous research enterprise and currently receive most of the funds for research, and (b) support for development of infrastructure for other schools (e.g., by leveraging NIDCR funds with other NIH components such as NCRR). The Council noted, in particular, that no dental schools are participating in the Research Endowment Program or the Centers of Excellence program which are offered by the NIH's National Center on Minority Health and Health Disparities and provide funds for development of infrastructure. The Council also suggested that dental schools might need to be innovative in their recovery of indirect costs and leveraging of debt to support development of infrastructure.

VII. CONCEPT CLEARANCES

NIDCR staff presented four concepts for the Council's consideration.

Gene Discovery for Craniofacial Disorders

Dr. Rochelle Small, Director, Developmental Biology & Mammalian Genetics Program, Division of Basic and Translational Sciences (DBTS), presented a draft RFA that is aimed at fostering creative approaches for the discovery of genes that cause or modify susceptibility to craniofacial, dental, and oral disorders. She noted that, in recent years, enormous progress has been made toward understanding single-gene disorders, but understanding complex gene disorders (e.g., non-syndromic cleft lip and palate) is much more difficult. The opportunities to elicit additional research on these disorders are now richer because of the vast amount of genomic data available and the new understanding that is being gained about genetic polymorphisms in populations and the role of different mutations in gene expression and selection. The proposed RFA, which the NIDCR plans to release in FY 2002 and fund in 2003, would encourage research specifically to identify genes that produce craniofacial disorders, modifier genes that influence risk, and environmental conditions that alter gene expression and modify susceptibility in diverse genetic backgrounds. The NIDCR anticipates using two funding mechanisms to support this research: investigator-initiated research project grants (R01s) and exploratory/developmental research grants (R21s).

The Council commented that the RFA was very well conceived and unanimously approved the concept.

Stem Cells in Development/Repair of Orofacial Structures

Dr. Eleni Kousvelari, Chief, Cellular and Molecular Biology, Physiology, and Biotechnology Branch, DBTS, presented a proposed RFA to foster research on embryonic and adult stem cell biology that

could help elucidate the complex events that occur during oral, dental, and craniofacial development and disease, as well as the repair and restoration of affected tissues. She noted that the NIH stem cell registry has approximately 60 cell lines available, which could be utilized to explore the development of craniofacial tissues and potential treatments for repair and regeneration. The two types of stem cells are both valuable for research: embryonic stem cells have the potential to develop into different types of cells, and adult stem cells have the capacity for self-renewal. The NIDCR anticipates using the R21 mechanism to supports these exploratory and developmental studies.

The Council applauded the NIDCR for developing this initiative because of the major breakthroughs possible with the use of stem cells for research. The Council unanimously approved the concept.

Management and Oversight for NIDCR Clinical Studies/Trials - Extramural Program

Dr. Margo Adesanya, Senior Scientist and Program Director, Patient-Oriented Research Program, Division of Population and Health Promotion Sciences, presented a proposed Request for Proposal (RFP) to obtain technical support, under contract, for NIDCR clinical research activities (e.g., clinical trials, registries, observational studies) in areas where current staffing and resources for managing research are limited. Dr. Adesanya noted that the NIDCR is proposing this initiative to facilitate the Institute's management and oversight of the increasing number and complexity of NIDCR-funded grants and contracts supporting clinical studies. The NIDCR currently funds 22 clinical trials—more than twice the number 2 years ago—each of which is required to have a Data Safety Monitoring Board for which staff provide logistical and administrative support. To ensure that the clinical research is of high quality, the NIDCR also provides oversight on important aspects such as regulatory issues, safety and protection of human subjects, and integration of clinical data. Staff noted that many ICs have similar support contracts to improve their efficiency in managing the clinical research process.

After discussion to clarify the nature and purpose of the proposed contract, the Council unanimously approved the concept.

Planning Awards for Research Infrastructure and Capacity Building in Dental Schools

Dr. Martinez presented a proposed initiative (RFA) for enhancing the research infrastructure and building research capacity at dental schools. The NIDCR proposes to support exploratory grants (P20s) for the development and initial implementation of institutional plans to strengthen the research programs in dental schools by helping to create a critical mass of researchers in a pre-selected area and to improve research infrastructures (facilities and equipment). The NIDCR developed this initiative to help meet the needs of dental schools identified at the October 2001 meeting of dental school deans (see sections IV and VI above). Dr. Martinez noted that the 3-year awards would be made in two phases: a 1-year planning phase, during which awardees would develop a comprehensive plan based on an assessment of needs and a school-wide evaluation, and a 2-year implementation phase to recruit and integrate additional scientists, support "magnet" investigators, create or renovate research facilities, developed shared research cores, and purchase modern research equipment.

In extensive discussion, the Council suggested that the wording of the initiative be modified to clarify that applicants' plans should include (a) identification of the area(s) of research that will be developed

and enhanced (i.e., further developed, not created *de novo*); and (b) outcome measures of accountability. The Council also suggested that the proposed RFA be modified to: (a) specify that it is intended specifically for dental schools, not dental researchers; (b) more clearly emphasize its long-term goals; (c) add focus on health disparities (within element 5 of the concept) and health services research; and (d) explicitly suggest the possibility of partnerships between schools. The Council expressed concern that some schools, which do not already have a significant research infrastructure, will have difficulty responding to the RFA and preparing an application. Dr. Tabak noted that the proposed RFA is intended for all dental schools, that those which are less research intensive could partner with those that are more research intensive, and that the initiative will be complemented in the future by other NIDCR actions.

The Council unanimously approved the concept.

VIII. NIDCR VIDEO - "SCIENCE KNOWS NO COUNTRY: NIDCR'S GLOBAL MISSION"

Dr. Lois K. Cohen, Director, Office of International Health (OIH), OD, introduced the new NIDCR video, which dramatically conveys the global reach of research on oral, dental, and craniofacial diseases (see section IV above). The video begins with Dr. David E. Barmes, former Special Expert for International Research, OIH, calling for international collaboration to "build science." Dr. Barmes notes that bacteria and viruses know no boundaries, and he cites six priority topics that cross national boundaries and need to be addressed through international research. The six topics are: infectious and emerging infectious diseases (e.g., orofacial gangrene, or noma, and HIV/AIDS), craniofacial anomalies (e.g., cleft lip and palate), optimum levels of fluoride, oral cancer, biomaterials and biomimetics, and reduction of health disparities.

The video highlights researchers who are working in the field to resolve the devastating medical and social problems of noma and cleft lip and palate. It conveys the need for broad collaboration internationally to advance research and improve health, the importance of educating parents and the public about the signs and symptoms of disease, the often complex interaction between genes and environment, the roles of behavior and poverty and malnutrition in disease, and the valiant efforts of researchers to improve the lives of individuals in immediate and direct ways. The video well demonstrates that international research has direct implications for the United States and offers the best science conducted in the most cost-effective way. The video is dedicated to the memory of Dr. Barmes (1931-2001), who made major contributions to international oral health research.

Dr. Cohen noted that, with the cooperation and support of the Friends of the NIDCR, copies of the video will be made available to all U.S. dental schools and others on request.

CLOSED PORTION OF THE MEETING

This portion of the meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

There was a discussion of procedures and policies regarding voting and confidentiality of application materials, committee discussions, and recommendations. Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect.

IX. REVIEW OF APPLICATIONS

Grant Review

The Council considered 303 applications requesting $62,191,305 in total costs. The Council recommended 236 applications for a total cost of $49,893,235 (see Attachment II).

ADJOURNMENT

The meeting was adjourned at 4:30 p.m. on January 28, 2002.

CERTIFICATION

I hereby certify that the foregoing minutes are accurate and complete.

_____	_____
Dr. Lawrence A. Tabak	Dr. J. Ricardo Martinez
Chairperson	Executive Secretary
National Advisory Dental and Craniofacial Research Council	National Advisory Dental and and Craniofacial Research Council

ATTACHMENTS

I. Roster of Council Members
II. Table of Council Actions
III. Director's Report to the NADCRC, January 2002

NOTE: A complete set of open-portion handouts is available from the Executive Secretary.